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EXAMINER

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The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/206,249  
Filing Date: December 07, 1998  
Appellant(s): SEIBERG ET AL.

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Andrea Colby  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3/17/2009 appealing from the Office action mailed 9/29/2008.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

#### **(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

#### **WITHDRAWN REJECTIONS**

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The rejection of claims 75-84 under 35 USC 102(a) as being anticipated by JP patent No. 410226642.

#### **(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

#### **(8) Evidence Relied Upon**

JP Hei-8-143442

Matsuura et al.

6/1996

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 75-84 are rejected under 35 U.S.C. 102 (b) as being anticipated by JP 408143442 (see the entire translation supplied by applicant especially the claims, paragraph 8, abstract).

JP 408143442 teaches a water extract of soybeans used to treat eczema. Whole soybeans are ground and water is added and then the extract is filtered. The ground matter is heated but to a temperature which could read on 5 °C.

### **(10) Response to Argument**

Appellant first argues that nowhere does JP 408143442 (hereafter JP '442) mention explicitly that the soybean extracts described therein contain active soy trypsin inhibitor proteins (STI).

Since STI are in soybeans and since the soybeans are not required to be heated to a temperature which would denature them (see claim 5 of JP '442) then it would have been inherent that the STI are in the extract of JP '442. Further as noted on page 16 of

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the instant specification, appellants admit that soybean milk contains STI which is clearly claimed by JP '442, see claim 6 of JP '442.

Appellant next argues that the soybean extract of JP '442 would not necessarily contain STI. Appellant turns to the declaration filed by Dr. Seiberg on July 30, 2008. Dr. Seiberg argues that the mere process of permitting soybeans to soak in water will not enable STI to diffuse into the soaking liquid. Dr. Seiberg refers to an article from 1947 by M. Kunitz. The declaration by Dr. Seiberg is referring to Table VI (page 305) of Kunitz which clearly is concerned with the chemical and physical properties of **crystalline** soybean trypsin inhibitor. Note also that the diffusion coefficient that Dr. Seiberg references only applies at 24 °C.

The instant claims and JP '442 are not dealing with **crystalline** soybean trypsin inhibitor. The enzyme trypsin has been **crystallized** in Kunitz but not in the instant invention or in JP '442. Further, only at 24 °C is the diffusion coefficient even valid. Thus, since the same STI is not even being compared since the instantly claimed STI and that of JP '442 are not crystalline then Kunitz is not even a valid reference for support from the Seiberg declaration thus making the Seiberg declaration invalid and inoperative as a declaration for appellant.

Further, it is noted in claim 6 of JP '442 that the soybeans are ground thus making it inevitable that an effective amount of STI will diffuse from soybeans into the soaking liquid in which it resides.

Next appellant argues that JP '442 indicates that the soaked soybean material is subjected to high heat, i.e. 80-100 °C and then sterilized at 120 °C. Appellant then

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references the declaration by Robert Zivin and argues that he states that exposure to high heat denatures, and thus deactivates, proteins such as STI. Appellants then concluded that one of ordinary skill in the art following JP '442 would therefore, not necessarily obtain a soybean extract that contains non-denatured soy trypsin inhibitory activity.

While this is noted it is also noted that claim 5 clearly indicates that the soybeans are heated at 5-100 °C for 5 minutes. Thus, the portion that Dr. Zivin is referring to is only one embodiment of the claimed invention of JP '442. Clearly JP '442 encompasses more than just the temperatures recited by Dr. Zivin such as 20-30 °C which would not denature the STI, see pages 6-7 of the translation, paragraphs 8 and 9.

Appellant then argues that allegedly according to JP '442, even if the STI remained intact in the soybeans throughout the processing steps described therein, it would not be present in the compositions that JP '442 describes. Appellant argues that that this is because the compositions described therein contain "extract liquid of soybeans".

While this is noted it is also very clear from JP '442 that "the water extract liquid is a filtrate obtained by filtering soymilk made from whole soybeans, dehulled soybeans or defatted soybeans with an ultrafiltration membrane", see claim 3 of JP '442. Further, claim 6 makes it clear that the preparation is made by **grinding whole soybeans, dehulled soybeans or defatted soybeans** thus making it clear that the soybean was ground making the STI available for diffusion into the water.

Appellant next argues that it is not the soybeans, but the liquid in which they have soaked which is the extract utilized in the composition of JP '442 but appellant's claims are drawn to a "non-denatured soy extract" and the water extracted soybean composition of JP '442 does result in a non-denatured soy extract since soybeans are the starting material, they are extracted with water and then the water is the soybean extract. Water is commonly used as a solvent to extract all kinds of plants and the resulting liquid is an extract of the plant. Thus, appellants are incorrect since JP '442 does teach a composition which is an extract of soybeans which would contain the claimed "non-denatured soy extract".

Next appellants argue that JP' 442 allegedly teaches that even in the instance in which there is a "protein fraction" generated by a process, this protein fraction is precipitated out of the extract that is to be used in topical compositions.

Upon closer inspection of paragraph 11 (where appellants are pointing to) it is clear that this is only done in the case where whey is generated as a by-product during the production of a soy protein isolate is used as a raw material. Claim 6 of JP '442 clearly does not require this. In fact claim 6 makes it very clear that no high heat is ever used and that the soybeans are crushed making it clear that water used as the solvent could easily release the STI and diffuse them into the extract. The STI of JP '442 and that of appellants is never crystallized as it is in Kunitz.

The only point in appellant's specification where they even attempt to define what they mean by STI is on page 16 of the instant specification where STI is noted as being



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“[N]atural compounds that inhibit trypsin, such as serine protease inhibitors, and in particular, soybean trypsin inhibitor ("STI"), can be used for this invention. Soybean extracts, limabean extracts and similar extracts, and other natural products made from soybean and the like, such as soybean milk, soybean paste, miso, trypsin inhibitor from soybean or limabean and the like, can also reduce phagocytosis by this mechanism. In the preferred embodiment, the naturally occurring composition is soy milk or STI.

Additional sources of serine protease inhibitors include, for example, the following plant families: Solanaceae (e.g., potato, tomato, tomatilla, and the like); Gramineae (e.g., rice, buckwheat, sorghum, wheat, barley, oats and the like); Cucurbitaceae (e.g., cucumbers, squash, gourd, luffa and the like); and, preferably, Leguminosae (e.g., beans, peas, lentils, peanuts, and the like)".

Clearly JP '442 teaches soy milk (see claim 6 of JP '442) which by definition is a soybean extract since claim 6 of JP '442 starts with soybeans thus making the resulting composition a soybean extract, which as defined by appellants in their own specification is what they mean by STI. Thus, since the STI was not denatured (heated) in claim 6, it is inevitable that the STI of JP '442 is still very much intact and thus very much still has viable STI activity. Note also that appellants in their own specification never qualify that the STI will not diffuse through any membrane and will in fact be in soymilk which claim 6 of JP '442 very much claims and defines very clearly to one of ordinary skill in the art.

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**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michael V. Meller/

Primary Examiner, Art Unit 1655

Conferees:

/Terry A. McKelvey/

Supervisory Patent Examiner, Art Unit 1655

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